

(d) *Audit or inspection.* A PACE organization must permit HCFA and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

- (1) Any aspect of services furnished.
- (2) Reconciliation of participants' benefit liabilities.
- (3) Determination of Medicare and Medicaid amounts payable.

§ 460.208 Financial statements.

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

- (1) A certification statement.
- (2) A balance sheet.
- (3) A statement of revenues and expenses.
- (4) A source and use of funds statement.

(c) *Quarterly financial statement—(1) During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If HCFA or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, HCFA or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

§ 460.210 Medical records.

(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

- (i) Be complete.
- (ii) Accurately documented.
- (iii) Readily accessible.
- (iv) Systematically organized.
- (v) Available to all staff.
- (vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Multidisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) Laboratory, radiological and other test reports.

(5) Medication records.

(6) Hospital discharge summaries, if applicable.

(7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(8) Enrollment Agreement.

(9) Physician orders.

(10) Discharge summary and disenrollment justification, if applicable.

(11) Advance directives, if applicable.

(12) A signed release permitting disclosure of personal information.

(13) Accident and incident reports.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.*

(1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.